งานบริหารและส่งเสริมการวิจัย
กองบริหารงานวิจัย มหาวิทยาลัยมหิดล
โทร. 02-849-6252 โทรสาร. 02-849-6247

ที่ อว 78.016/ว 2837
วันที่ 9 มิถุนายน 2565
เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการจากแหล่งทุน National Institutes of Health (NIH) หัวข้อ "NIH Research Project Grant: Partnerships for Development of Vaccines Against Select Enteric Pathogens (R01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-AI- 22-037
สิ่งที่ส่งมาด้วย 1. ประกาศทุน RFA-AI-22-037
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วย แหล่งทุน National Institutes of Health (NIH) ประเทศสหรัฐอเมริการ เปิดรับข้อเสนอโครงการหัวข้อ "NIH Research Project Grant: Partnerships for Development of Vaccines Against Select Enteric Pathogens (R01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-AI-22-037 โดย**เปิดรับข้อเสนอโครงการตั้งแต่วันที่ 14 สิงหาคม 2565 จนถึงวันที่ 14 กันยายน 2565 เวลา 17.00 น. ตามเวลาประเทศไทย** ทั้งนี้ โครงการที่เสนอขอทุน ให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่อง หลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักชวนแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่งทุนที่ https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-22-037.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย **โปรดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการภายในวันที่ 7 กันยายน 2565 ทั้งนี้ หากส่วนงานจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 7 กันยายน 2565 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว**

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

(ศาสตราจารย์ ดร. นายแพทย์ ภัทรชัย กีรติสิน)
รองอธิการบดีฝ่ายวิจัย

ผู้ประสานงาน : นางสาวจิตติพร นวลละออง
โทร 02-849-6252 อีเมล chittiporn.nua@mahidol.edu

ศูนย์บริหารงานวิจัยและนวัตกรรม
หลักฐาน
10 มิ.ย. 65

เรียน คณบดี (ผ่านรองฯ วิจัย)

- เพื่อโปรดทราบ มหาวิทยาลัยฯ ขอสนับสนุน การยื่นข้อเสนอโครงการเพื่อขอทุน NIH # ~~RFA~~-AI-22-037 ประเภทข้อเสนอโครงการใหม่ ตั้งแต่ วันที่ 14 ธ.ค. – 14 ก.พ. 2565 (17.00น.) ผู้สนใจเสนอขอทุนโปรดดาวน์โหลดเอกสาร NAZ BL เพิ่มเติมได้ตาม website ที่แจ้ง และจัดส่ง proposal ฉบับสมบูรณ์ พร้อมเอกสารอื่นๆ ตามที่มหาวิทยาลัยกำหนด ก่อน วันที่ 6 ก.พ. 2565
- สรุปรายชื่อสนับสนุนทุนวิจัย
- ส่งเรื่องคืนผู้ประสานงานวิจัย

ขอแสดงความนับถือ
13 มิ.ย. 65
ดร. ปิยนาถ
13/6/65

ทราบ
14 มิ.ย. 2565

รับเรื่องคืนจากห้องคณบดี+รองคณบดี
วันที่ 14 มิ.ย. 2565

ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

1. ผู้สมัครขอรับทุนศึกษาประกาศทุน (Funding opportunity announcements หรือ FOA) อย่างละเอียด ตรวจสอบกำหนดการส่งข้อเสนอของมหาวิทยาลัย และสืบค้นข้อมูลที่เกี่ยวข้องกับงานวิจัยของตนเองผ่าน NIH RePORTER https://reporter.nih.gov
2. ผู้สมัครแจ้งข้อมูลเข้ามายังกองบริหารงานวิจัย ทางอีเมล chittiporn.nua@mahidol.edu เพื่อขอเปิดบัญชี eRA commons และขอสร้างข้อเสนอโครงการในระบบออนไลน์ ASSIST ของแหล่งทุน NIH โดยแจ้งข้อมูลดังนี้

   Name:

   Surname:

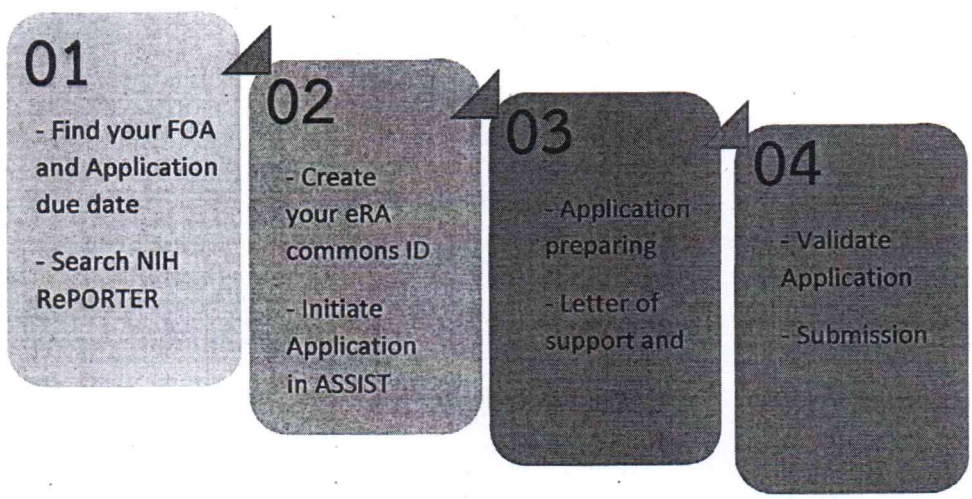
   Email (XXXX@mahidol.ac.th หรือ XXXX@mahidol.edu):

   Funding Opportunity Announcement (FOA) Number:

   Application title:

   Application due date:
3. มหาวิทยาลัยสร้างบัญชี eRA commons และสร้างข้อเสนอโครงการในระบบ ASSIST ให้ผู้สมัครขอรับทุน ผู้ขอรับทุนจัดทำข้อเสนอโครงการและเอกสารที่เกี่ยวข้องตามข้อกำหนดของแหล่งทุนร่วมกับมหาวิทยาลัย
4. ผู้สมัครขอรับทุนนำส่งเอกสารข้อเสนอโครงการฉบับสมบูรณ์ผ่านหัวหน้าส่วนงานเพื่อขออนุมัติจัดส่งข้อเสนอโครงการผ่านระบบออนไลน์ ASSIST ตามกำหนดรับข้อเสนอของมหาวิทยาลัย** กองบริหารงานวิจัยตรวจสอบข้อเสนอโครงการ เสนออนุมัตินำส่งข้อเสนอโครงการและจัดส่งข้อเสนอโครงการในนามของมหาวิทยาลัยไปยังแหล่งทุน

(**หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)



สอบถามข้อมูลเพิ่มเติม คุณจิตติพร 02-8496252 chittiporn.nua@mahidol.edu
หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ
Mahidol University: Supporting Unit for International Research Funding (MU: SURF)

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

Funding Opportunity Title

Partnerships for Development of Vaccines Against Select Enteric Pathogens (R01 Clinical Trial Not Allowed)

Activity Code

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-AI-22-037

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855

Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to solicit research applications focused on advancing development of vaccine candidates against Enterotoxigenic *Escherichia coli* (ETEC), *Salmonella enterica* serotype Paratyphi A, and two *Shigella* species, *Shigella flexneri* and *Shigella sonnei*.

Key Dates

Posted Date

May 10, 2022

Open Date (Earliest Submission Date)

August 14, 2022

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
September 14, 2022	Not Applicable	Not Applicable	February 2023	May 2023	June 2023

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

September 15, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-AI-22-037) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to solicit research applications for projects focused on advancing development of vaccine candidates against Enterotoxigenic *Escherichia coli* (ETEC), *Salmonella enterica* serotype Paratyphi A, and two *Shigella* species, *Shigella flexneri* and *Shigella sonnei*.

Background

The National Institutes of Health (NIH) and other agencies in the Department of Health and Human Services (DHHS) support development of countermeasures to protect the public from infectious diseases. The National Institute of Allergy and Infectious Diseases (NIAID) established the Partnerships program to support discovery, preclinical research, product development and eventual commercialization of candidate products that address specific pathogens/agents. This FOA reflects priorities for further development of vaccines against select NIAID high priority Category B enteric bacteria responsible for a high burden of diarrheal disease globally, specifically – ETEC, *Salmonella enterica* serotype Paratyphi A, *Shigella flexneri* and *Shigella sonnei*. These three genera of food- and water-borne bacterial pathogens significantly impact public health and often lead to deleterious, lifelong consequences that negatively impact physical health and cognitive development, especially for infants and children. Vaccines are needed for primary prevention of disease caused by these high priority enteric bacteria, and this FOA focuses on milestone-driven research to advance existing vaccine candidates towards clinical studies. Further, *Salmonella* and *Shigella* are listed at the Serious threat level in the Centers for Disease Control and Prevention's (CDC) 2013 and 2019 reports on Antibiotic Resistance Threats in the United States (https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf), which cite urgent need to combat multi drug resistant (MDR) strains.

The World Health Organization (WHO) published the ETEC vaccine Preferred Product Characteristics (PPC) (https://www.who.int/publications/i/item/who-preferred-product-characteristics-for-vaccines-against-enterotoxigenic-escherichia-coli) in August 2021, and the Shigella vaccine PPC (https://www.who.int/publications/i/item/9789240036741) in November 2021. Thus, researchers have an opportunity to align their proposed projects with WHO PPCs.

Research Objectives, Goals, and Scope

Vaccines play a critical role in the primary prevention of infectious diseases. The objective of this FOA is to support milestone-driven preclinical research that will advance the development and/or production of candidate vaccine(s) for these select enteric pathogens. The initiative will support development of candidate vaccines that target specific pathogens and/or multivalent forms.

Development of candidate vaccines should begin with previously identified, well-characterized immunogens for lead optimization and downselection. Projects are expected to include proof-of-concept studies in animal or three-dimensional (3D) human-derived tissue models, preclinical evaluation, and, if warranted, process development and scale-up production under cGMP to provide sufficient quantities for pre-clinical Food and Drug Administration (FDA)-required animal model studies and early preclinical evaluations. Standard Investigational New Drug (IND)-enabling activities are encouraged for advanced vaccine candidate(s.)

Each application must propose a late-stage research and development project whose goal is to advance an already identified lead candidate(s) toward clinical studies. Proposed projects are not required to result in a "final" product, nor is it necessary to propose completion of the product development process up to the point of readiness for clinical trials or validation within the time frame of the project. Applications that would significantly advance candidate product(s) toward clinical or field usefulness are responsive and encouraged. Required industrial participation on applications from academic institutions (see below) will facilitate appropriate and validated product development activities. Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) are strongly encouraged to obtain expertise in the areas of product development planning and target product profile development in general, and regulatory matters in particular. Expertise needed to fulfill project objectives may be included as defined effort or as periodic consultation on specific issues. Targeted product development efforts are encouraged to be conducted in close partnership with experienced vaccine developers, nongovernmental organizations, or industrial collaborators.

Specific areas of Research Interest

For all vaccine projects, approaches should consider the ultimate potential of a candidate vaccine to quickly induce safe and protective responses in diverse domestic and international populations. Vaccine projects may include, but are not limited to, one or more of the following product development activities:

- Innovative modifications to extend pathogen scope and/or efficacy, e.g., combination vaccines;
- Optimization of delivery platforms, antigen and adjuvant combinations/formulations;
- Comparison of vaccine candidate(s) to downselect candidates for further development;
- Lead vaccine candidate optimization;
- Evaluation of efficacy in challenge models where appropriate animal models are available;
- Optimization of dose and route of delivery in preclinical evaluations;
- Optimization of production methodology including process development;
- Scale up and production of candidate vaccines including cGMP production;
- Process development for the production of vaccine components, including Quality Assurance (QA)/Quality Control (QC), methods for product recovery, characterization, purification, identity, and stability;
- Manufacturing under GLP or cGMP to produce quantities sufficient for preclinical and early clinical evaluations; and
- Performing preclinical testing for safety, toxicity, and efficacy in animal models and other benchmarks required for successful submission and review of an IND application by the FDA.

Industrial Participation

All projects submitted by academic institutions to this FOA must include substantive investment by at least one industry participant. For the purpose of this FOA, "industry" is defined as a large or small, domestic or foreign, pharmaceutical, biotechnology, bioengineering, or chemical company, or a related non-profit entity with an established track record in product development, and "substantive investment" is defined as a significant commitment of one or more resources to the project including, but not limited to: project and product development guidance/support (consultation), personnel, in kind contributions of materials and/or reagents (i.e., innovative biotechnology platforms, scale up of cGMP chemical synthesis or production, etc.), provision of animal or other laboratory models for evaluation, subcontracts, data management resources, regulatory support, or alterations/renovations of facilities or provision of equipment to address biohazard concerns. For projects with consultation-only investment, the industrial partner must commit a specific level of effort (concomitant to stage of preclinical and/or product development activities) that is included in the requested budget. Support for industrial partner activities may be included in the project budget. There is no requirement for an academic participant on applications submitted by industrial organizations.

Applications including the following will be considered non-responsive and will not be reviewed:

- Projects focusing on discovery-based studies, such as identification of new antigens.
- Projects lacking appropriate proof-of-concept data supporting the targeted immunogens or candidate vaccine(s).
- Projects from academic institutes that lack substantive investment by at least one industry participant.
- Applications that focus on vaccine candidates for pathogens other than Enterotoxigenic *Escherichia coli* (ETEC), *Salmonella enterica* serotype Paratyphi A, *S. flexneri*, or *S. sonnei*.
- Applications that propose clinical trial(s). While clinical development strategies may be included within an overall project, this FOA will NOT support clinical trials.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIAID intends to commit $ 5.2 million in FY 2023 to fund 4-6 awards.

Award Budget

A budget for direct costs of up to $750,000 per year may be requested.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Government

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. SAM registrations prior to fall 2021 were updated to include a UEI. For applications due on or after January 25, 2022, the UEI must be provided on the application forms (e.g., FORMS-G); the same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://era.nih.gov/) - Once the unique organization identifier (UEI after April 2022) is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to

identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. See, e.g., Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar.))

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Annie Walker-Abbey, Ph.D.

Telephone: 240-627-3390

Email: aabbey@niaid.nih.gov (mailto:aabbey@niaid.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Other Attachments: Applicants are required to include a Product Development Strategy that includes both a "Milestones and Timeline" and a "Product Development Plan" section. The Product Development Strategy attachment must be in pdf format with a filename of "Product_Development_Strategy.pdf". Applications lacking a required section of the Product Development Strategy section will be deemed incomplete and will not be reviewed.

The overall Product Development Strategy, made up of the "Milestones and Timeline" and the "Product Development Plan sections," is limited to 12 pages.

Milestones and Timeline: Applicants are required to provide detailed project performance and timeline objectives in a section entitled "Milestones and Timeline." This section must be no more than 5 pages and must include:

- A clear description of all interim objectives (research and/or developmental milestones) to be achieved during the course of the project. Applicants also must identify any impediments that could require a revision in the work plan or milestones with a discussion of alternative approaches.
- Detailed quantitative criteria by which milestone achievement will be assessed.
- A detailed schedule or timeline for the anticipated attainment of each milestone and the overall goal(s).

Product Development Plan: Applicants are required to provide detailed development plans in a section entitled "Product Development Plan". This section must be no more than 7 pages and must include:

- A statement of the intended use/indication of the proposed product and public health gap the product is intended to fill.
- A statement of the value of the project, including lay description of key technology objectives, innovation, and advantages compared to competing products, technologies, or services.
- A clear description of the goal(s) of the project, including one (or more) intermediate products (tools), final product(s) or stage(s) of product development to be completed during the award period. A specific final product profile that is intended for licensing indication is not requested.

Additionally, the Product Development Plan must include descriptions pertaining to preclinical product development activities pertaining to the product proposed. For the purpose of this FOA, "preclinical" is defined as all activities beyond lead candidate identification.

Product Development Plans should summarize:

- The performance specifications and features the product should have in order to provide immunological benefit.
- A description of the candidate product or lead series as it is currently configured.
- A description and developmental status of the assays for product release and characterization, including activity and efficacy.
- Data that support the characterization and selection of the candidate product for further development, including a summary of data that demonstrates efficacy in in vitro assays and/or in vivo models for one or more of the selected agent(s). This includes: a detailed description of the assays and animal models, the choice of pathogen challenge, strain and route, and a rationale for the choice of animal model, pathogen challenge, strain and route, as well as for the outcome/endpoints selected; documentation that the animal infection experiments were performed under well-controlled experimental conditions.
- Discussions with FDA, if any, that are relevant to development activities for the candidate product/technology.

When appropriate, and as part of the Product Development Plan, applicants should document compliance with guidelines that govern GLP, as defined by 21 CRF (58), and cGMP, as defined by 21 CRF (211), manufacturing and/or IND/IDE enabling studies that will be performed under the project award as they would be applicable to eventual product licensure in the U.S.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

For projects with consultation-only investment, the industrial partner must commit a specific level of effort (concomitant to the stage of preclinical and/or product development activities) that is included in the requested budget. Support for industrial partner activities may be included in the project budget.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: Applications must propose development of a candidate vaccine, including corresponding proof-of-concept data demonstrating feasibility. Provide a rationale for the proposed vaccine based on stage of development. All applications should include in the Research Strategy:

- A clear description of how the project will significantly advance the development and/or production of a vaccine;
- A clear description of the capabilities of the candidate vaccine;
- A description of how the plan represents the best use of current or emerging technologies and appropriate collaborations to achieve the project objectives;
- Plans for determining the sensitivity, specificity and validation of the candidate vaccine.

Industry Participation: For applications from academic institutions, identify the industrial partner(s) and describe the organization's participation and investment in the project. All applications submitted by academic institutions must demonstrate substantive investment and participation in the project by at least one industry participant. There is no reciprocal requirement for applicants from industrial organizations to include an academic partner.

Applications from academic institutions should include in the Research Strategy:

- A clear description of the role of the industrial partner(s) and associate participation and investment in the project;
- A clear description of how the project leverages industry involvement to accelerate diagnostic platform development.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential fieldof the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the unique entity identifier (UEI) provided on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA

Is this project likely to significantly advance the development of a candidate vaccine against one or more of the select pathogens identified in this initiative?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA

For applications from academic institutions, does the applicant describe the substantive investment and participation in the project of an industry participant? Will the industrial participation facilitate candidate product development and achievement of proposed objectives?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this FOA

Is the research and development plan supported by strong proof-of-concept data that is appropriate for the candidate vaccine(s) and targeted pathogen(s)?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Product Development Strategy

Is the Product Development Strategy well-conceived and appropriate for the proposed countermeasure category? Are the Milestones and Timelines proposed to achieve the goals of the project appropriate and feasible? Does the applicant propose quantitative criteria by which the milestones achievement will be assessed and are the criteria relevant for assessing the proposed product development? Is the proposed Product Development Plan feasible and appropriate for proposed and future product development?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (https://grants.nih.gov/grants/policy/model_organism/); and (3) Genomic Data Sharing Plan (GDS) (https://osp.od.nih.gov/scientific-sharing/policies).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Allergy and Infectious Diseases (NIAID), in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm)of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council.. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.htm).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159), including of note, but not limited to:

- Federalwide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity , sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-

topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html)and https://www.lep.gov (https://www.lep.gov/).

- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

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Financial/Grants Management Contact(s)

Vandhana Khurana
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-2966
Email: khuranav@niaid.nih.gov (mailto:khuranav@niaid.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?05-13-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).